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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,423

09/10/2003

Tammy Burd Mehta

100/03021

4629

21569 7590 05/14/2008

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,423	Applicant(s) MEHTA, TAMMY BURD	
	Examiner CHRISTOPHER M. BABIC	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claim(s) 1 and 3-10 are pending. The following Office Action is in response to Applicant's communication dated November 21, 2007.

Claim Rejections - 35 USC § 112 - Indefiniteness - Withdrawn

Applicant's claim amendments are sufficient to overcome the rejection of claims 1 and 3-10. Thus, the rejection has been withdrawn.

Claim Rejections - 35 USC § 103 - Withdrawn

Applicant's claim amendments are sufficient to overcome the rejection of claims 1 and 3-10 over Lipshutz, Chetverin, and Moss. Thus, the rejection has been withdrawn. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103 - New Grounds

The following rejection(s) are made in view of Applicant's claim amendments.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim(s) 1, 3-5, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. 5,856,174) in view of Chetverin et al. (U.S. 5,616,478), in further view of Weissman et al. (U.S. 6,395,887 B1).

With regard to claim(s) 1 and 8-10, Lipshutz teaches methods of performing amplification (col. 6-8, amplification, for example) and capillary electrophoresis (col. 11-12, capillary electrophoresis; col. 12, lines 30-50, sieving mediums, for example) within microfluidic devices (fig. 3; col. 14, lines 10-35, for example).

With specific regard to the claimed invention requiring PCR and separation in a "channel" of a microfluidic device, Applicant is reminded that the term "channel" is not defined in any structurally limiting manner. In fact, figure one of the specification provides a device that can be considered to contain a "channel" comprising a chamber 107 followed by a thin fluid passage 103. It is submitted that the device embodiments taught in Lipshutz encompass such a "channel" limitation. First, Lipshutz expressly teaches that PCR and electrophoretic separation can occur in succession within the microfluidic device (col. 4 lines 20-45, for example). Next, Lipshutz teach that reactions may be performed within fluid passages or "channels" (col. 13, 60-65, for example). Furthermore, Lipshutz expressly teaches performing capillary electrophoresis in a fluid "channel" (col. 11-12, for example). Thus, it is submitted that Lipshutz envisions performing an integrated PCR and capillary electrophoresis in a single "area", "channel", or "chamber" within a microfluidic device.

With regard to the above claims, Lipshutz does not expressly teach performing amplification reactions within an unpolymerized medium, and subsequent separation of the amplification products by flowing the product through the polymerized form of the sieving medium, within the claimed polymer concentration, i.e. comprising a polymer concentration that is less than 0.4%.

Chevretin provides a supportive disclosure that teaches the amplification of nucleic acids within sieving mediums (col. 4-6, summary, for example) such as those comprised of different acrylamide mediums (col. 12, for example). Example 3 of Chevretin expressly teaches the amplification of nucleic acid within a sieving medium before it is cast, i.e. polymerized into a solidified substance (col. 18-19; col. 19, lines 30-40, for example). Chevretin further teaches that sieving mediums may be impregnated with amplification enzymes before casting to prevent problems to due harsh polymerization conditions (col. 12, lines 30-40, for example). Thus, the teachings of Chevretin at the very least provide motivation for one to perform a PCR reaction before polymerization to prevent loss of enzyme activity due to harsh polymerization conditions.

With regard to claim(s) 7, Chevretin teaches thermostable DNA polymerase, (col. 19, lines 25-35, *thermus thermophilus*, for example).

None of the references outlined above expressly teach the claimed polymer concentration, i.e. comprising a polymer concentration that is less than 0.4%.

It is first submitted that the optimization of polymer concentrations for use in nucleic acid separation electrophoresis procedures was well known in the art at the time of invention as demonstrated by Lipshutz (col. 12, lines 35-45, for example).

Weissman provides a supportive disclosure that teaches a nucleic acid separation electrophoresis procedure comprising a polymer concentration that is less than 0.4% (col. 2, 0.2% polyacrylamide, for example).

With regard to claim(s) 3-5, Moss teaches a polymer concentration that is less than 0.4% (col. 2, 0.2% polyacrylamide, for example).

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to simply amplify and separate nucleic acids products within well known electrophoresis acrylamide polymer concentrations of less than 0.4% polymer within microfluidic devices since the prior art demonstrates that such amplification within polymers can take place and reduce experimentation time by combining the two procedures.

Furthermore, Applicant is reminded that persons of varying degrees of skill not only possess varying bases of knowledge, they also possess varying levels of imagination and ingenuity in the relevant field, particularly with respect to problem-solving abilities. Thus, it would have been *prima facie* obvious to a skilled artisan at the time of invention to simply perform a PCR reaction before polymerization of a present sieving medium to prevent loss of enzyme activity due to harsh polymerization conditions.

2. Claim(s) 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (U.S. 5,856,174) in view of Chetverin et al. (U.S. 5,616,478), in further view of Weissman et al. (U.S. 6,395,887 B1) as applied to claim 1 above, and further in view of Dubrow (U.S. 5,164,055).

The teachings of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach polymers comprising polyethylene oxide.

Dubrow provides a supportive disclosure that teaches a nucleic acid separation electrophoresis procedure utilizing polymers comprising polyethylene oxide (col. 14, lines 40-60; col. 17, lines 35-55, for example). Thus, the use polymers comprising polyethylene oxide for nucleic acid fractionation was well known in the art at the time of invention.

Thus, in summary, it is submitted that it would have been *prima facie* obvious to a skilled artisan at the time of invention to utilize polyethylene oxide within electrophoresis gels since the prior art demonstrates the molecule as useful in such a capacity.

Conclusion

Claim(s) 1 and 3-10 are rejected. No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Woolley et al. ("Functional integration of PCR amplification and capillary electrophoresis in a microfabricated DNA analysis device" Anal Chem. 1996 Dec 1;68(23):4081-6). Woolley teaches integrated PCR and electrophoresis within a microfluidic device; however, is silent with regard to performing PCR within a polymer solution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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